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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,451	09/09/2003	Maria Villani	14431-16	4939
45200	7590	12/06/2005	EXAMINER	
PRESTON GATES & ELLIS LLP 1900 MAIN STREET, SUITE 600 IRVINE, CA 92614-7319			VANIK, DAVID L	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 12/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/659,451

Applicant(s)

VILLANI, MARIA

Examiner

David L. Vanik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 10-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 23-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 7/28/04; 9/29/05
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Receipt is acknowledged of the Applicant's Remarks and Amended Claims filed on 9/22/2005.

The 35 USC §102 rejection over DE 4028622 is hereby **withdrawn**. As a result of Applicant's amended claims, the 35 USC §102 rejection over US Patent 6,821,264 ('264) is hereby **withdrawn**.

The 35 USC §102 rejection over RU 2176511 ('511) is hereby **maintained**. Additionally, the 35 USC §103 rejection over RU 2176511 ('511) in view of US Patent 3m896,238 ('238) is hereby **maintained**.

### ***Priority***

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 10/186996, fails to provide adequate support or enablement in the manner provided by the first paragraph

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of 35 U.S.C. 112 for one or more claims of this application. As a result, the examiner is construing the priority date to be 9/9/2003.

### **MAINTAINED REJECTIONS:**

The following rejections are maintained. As a result of Applicant's claim additions, newly added claims 23-25 are rejected over RU 2176511 ('511).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-4, 7-8, and 24-25 are rejected under 35 U.S.C. 102(a) as being anticipated by RU 2176511 C1 ('511).

'511 disclose a dermatological composition comprising a Porifera-derived material, a fresh-water sponge of the *Spongillidae* family, and ethyl alcohol, a pharmaceutically acceptable excipient (abstract). As a the fresh-water sponge-based composition is a water-ethanol extract, the composition comprises both ethanol and water. Additionally, the fresh-water sponge-based composition may be included in

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lotions, gels, creams, and cosmetic masks (page 4). It should be noted that claims 1 and 7 are product-by-process claims. As such, claims 1 and 7 will be treated as product claims and not as method claims. By disclosing a composition comprising a Porifera-derived product, a fresh-water sponge of the *Spongillidae* family, the composition advanced by '511 et al anticipates the instant claims 1 and 7 (abstract).

The claims are therefore anticipated by 2176511 C1 ('511).

### ***Response to Arguments***

Applicant's arguments filed on 9/22/2005 have been fully considered but they are not persuasive. In response to the 4/27/2005 Non-Final Rejection, Applicant has asserted that 'the '511 does not teach "substantial pure" Porifera species powder because the '511 composition comprises sponge that has been extracted by 40-70% ethanol in water for 20-40 days. The examiner respectfully disagrees with this assertion.

As defined by Applicant in paragraph 0085 of the instant application, "substantially pure refers to a natural product, specifically a Porifera sp. that has been separated from environmental debris including rocks, sticks, other marine life etc." As interpreted from paragraph 0085, this definition of "substantial pure" serves to distinguish Applicant's claimed invention from that practiced by "native people." Interpreted in this light, the fresh-water sponge-based composition described by '511 is "substantially pure." That is, the fresh-water sponge-based composition of the

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*Spongillidae* family advanced by '511 "has been separated from environmental debris including rocks, sticks, other marine life etc." As such, the '511 composition is "substantially pure" according to Applicants' definition.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over 2176511 C1 ('511) in view of US patent 3,896,238 ('238).

'The teachings of '511 are discussed above. '511 does not disclose a kit for packaging a skin treating composition.

'238 disclose an anti-acne composition and kit for packaging said composition (column 23, lines 2-65). Depending on the intended use, one of ordinary skill in the art would have been motivated to package a composition, such as an anti-acne composition, in a kit. Kits provide a convenient mechanism to disperse products to consumers. By combining the teachings of '238 with those of '511 and producing a kit comprising an anti-acne composition, there is a reasonable expectation that said kit would provide a convenient mechanism to disperse an anti-acne product to consumers. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to package an anti-acne composition, such as the one advanced in the instant application, in a kit.

### ***Response to Arguments***

Applicant's arguments filed on 9/22/2005 have been fully considered but they are not persuasive. In response to the 4/27/2005 Non-Final Rejection, Applicant has asserted that 'the '511 does not teach "substantial pure" Porifera species powder because the '511 composition comprises sponge that has been extracted by 40-70% ethanol in water for 20-40 days. The examiner respectfully disagrees with this assertion.

As defined by Applicant in paragraph 0085 of the instant application, "substantially pure refers to a natural product, specifically a Porifera sp. that has been

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separated from environmental debris including rocks, sticks, other marine life etc.” As interpreted from paragraph 0085, this definition of “substantial pure” serves to distinguish Applicants’ claimed invention from that practiced by “native people.” Interpreted in this light, the fresh-water sponge-based composition described by ‘511 is “substantially pure.” That is, the fresh-water sponge-based composition of the *Spongillidae* family advanced by ‘511 “has been separated from environmental debris including rocks, sticks, other marine life etc.” As such, the ‘511 composition is “substantially pure” according to Applicants’ definition.

As stated above, kits provide a convenient mechanism to disperse products to consumers. By combining the teachings of ‘238 with those of ‘511 and producing a kit comprising an anti-acne composition, there is a reasonable expectation that said kit would provide a convenient mechanism to disperse an anti-acne product to consumers. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to package an anti-acne composition, such as the one advanced in the instant application, in a kit.

#### **NEW REJECTIONS:**

##### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.



Claims 1-9 and 23-25 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The instant claims 1-9 and 23-25 are directed to a composition comprising a “substantially pure powder of a Porifera species.” It is the examiner’s position that a “substantially pure powder of a Porifera species” is a product of nature and, as such, is considered non-statutory subject matter. As confirmed in *Diamond v. Chakrabarty*, patentable subject matter includes “anything under the sun made by man” (*Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980)). Since “substantially pure powder of a Porifera species” is a product of nature and is not formed by the “hand of man,” it is the examiner’s position that it is considered non-statutory subject matter.

### ***Correspondence***

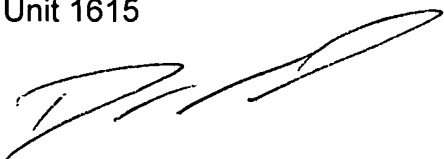
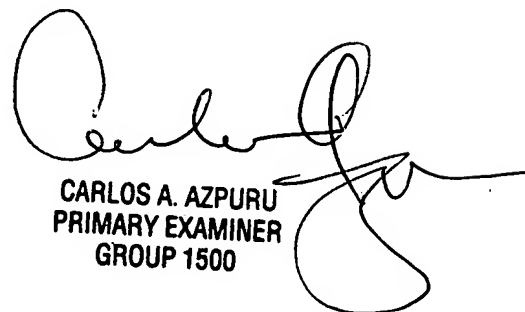
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Vanik whose telephone number is (571) 272-3104. The examiner can normally be reached on Monday-Friday 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Carlos Azpuru, can be reached at (571) 272-0588. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Vanik, Ph.D.  
Art Unit 1615

  
11/25/05  
CARLOS A. AZPURU  
PRIMARY EXAMINER  
GROUP 1500